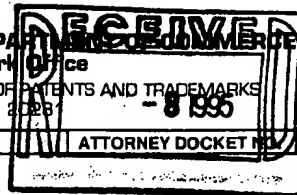




UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR
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08/182,183 05/23/94 LTN

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18N2/0505

SYNE225/C4-U
EXAMINER

GUEST CERMAK, S

ART UNIT PAPER NUMBER

16

1812
DATE MAILED:

05/05/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 11/7/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-74 are pending in the application.
Of the above, claims are withdrawn from consideration.
2. ☐ Claims have been cancelled.
3. ☐ Claims are allowed.
4. ☐ Claims are rejected.
5. ☐ Claims are objected to.
6. ☒ Claims 1-74 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-23, 39-40, 56-59, drawn to a GDNF protein, classified in Class 530, subclass 399 and class 514, subclass 12.

Group II. Claims 24-25, drawn to a biochemical purification method, classified in Class 530, subclass 417.

Group III. Claims 26-36, 42-55, drawn to DNA encoding GDNF, host cells and a recombinant method of production, classified in Class 536, subclass 23.5, class 435, subclasses 320.1 and 69.1..

Group IV. Claims 37-38, 41, and 63-69, drawn to a method of treating a patient using GDNF, classified in Class 514, subclass 12.

Group V. Claims 60-62, drawn to an antibody, classified in Class 530, subclass 389.2.

Group VI. Claims 70-74, drawn to a implantation device , classified in Class 604, subclass 890.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and I are related as a DNA molecule which encodes a protein molecule. The purpose of the DNA molecule is to produce the protein in recombinantly produced host cell. Although the DNA molecule and the protein are related since the DNA encodes for the specific claimed protein, they are distinct inventions requiring separate searches. Furthermore, the protein

product can be made by another and materially different process, such as by synthetic peptide synthesis or biochemical purification. For this reason the DNA are distinct from the protein.

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the protein can be made another and materially different process such as by synthetic peptide synthesis or biochemical purification.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the protein can be used in a materially different process of using such as *in vitro* cell culture.

The invention of group V is related to the invention of group I as an antibody raised to a protein. Although immunologically related, the inventions comprise two distinct proteins as evidenced by their primary, secondary, and tertiary structure. Therefore, the inventions are considered distinct.

The device of group VI is distinct from the GDNF protein used in the device because the GDNF protein can be administered in other forms.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, and because the searches for the individual Groups are not coextensive, restriction for examination purposes as indicated is proper.

A telephone call was made to Barry Swanson on April 25, 1995 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shelly Guest Cermak who can be reached by any of the following means:

Telephone	(703) 308-3154
Fax	(703) 305-3014 or 308-4227
Internet	scermak@uspto.gov or scermak@pioneer.uspto.gov


Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Examiner Cermak is generally available Mondays through Fridays from 9am to 5pm (Eastern). If she is not available to take a call, a message may be left on her voicemail. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Garnette D. Draper, can be reached on (703) 308-4232.

Note that papers of record may be submitted to Group 1800 by fax at either of the numbers noted above; refer to 1096 OG 30. Submission of a confirmation copy through the mailroom is not required; duplicate submissions are discouraged since entry of two copies of the same paper tends to confuse the record. Applicant should, however, retain on file the original copy of any formal paper which is submitted by fax.

Faxed messages which are not formal papers should reach the examiner promptly. To expedite their delivery, they should be clearly marked on the first page as INFORMAL COMMUNICATION, COURTESY COPY, or the like. It is also a good idea to call the examiner when an informal communication is faxed so she knows to expect it.

The examiner will check her E-mail messages at least every morning. There is at present no procedure which allows for the submission of formal communications to the PTO via E-mail.


Shelly Guest Cermak
Patent Examiner
Art Unit 1812

May 3, 1995